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510(k) Summary of Safety and Effectiveness

K123318
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SUBMITTER:	Covidien llc 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-5352
CONTACT PERSON:	Sarah Rizk Senior Product Specialist, Regulatory Affairs
DATE PREPARED:	October 19, 2012
TRADE/PROPRIETARY NAME:	iDrive™ Ultra powered handle and Endo GIA™ adapter
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staples
CLASSIFICATION NAME:	Staples, Implantable
PREDICATE DEVICE(S):	iDrive™ Ultra powered handle and Endo GIA™ adapter (K121510)
DEVICE DESCRIPTION:	This 510(k) introduces an accessory to the iDrive™ Ultra powered handle and Endo GIA™ adapter system (K121510), the iDrive™ Ultra reusable manual adapter tool. The iDrive™ Ultra reusable manual adapter tool is a reusable, handheld device that can be used to operate an Endo GIA™ adapter manually. It can be used to complete a firing, retract the knife and open the jaws, and to articulate an Endo GIA™ reload. The "manual tool" is not intended to initiate a reload firing. It is intended to provide the user with a manual method of operating the reload. In addition, this premarket notification reports non-significant changes made to the iDrive™ Ultra powered handle and Endo GIA™ adapter (K121510) since their clearance in July 2012. At the time of their implementation, these changes did not necessitate a 510(k) notification. These changes are described in this 510(k) according to the FDA Draft Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k)".
INTENDED USE:	The iDrive™ Ultra powered handle and Endo GIA™ adapter, when used with Endo GIA™ single use reloads have applications in abdominal, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature, and biliary structures and for transection and resection of pancreas. The iDrive™ Ultra powered handle and Endo GIA™ adapter, when used with Endo GIA™ curved tip single use reloads, can be used to blunt dissect or separate target tissue from other certain tissue.

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	The iDrive™ Ultra powered handle and Endo GIA™ adapter, when used with the Endo GIA™ Radial Reload with Tri-Staple™ Technology, has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.
TECHNOLOGICAL CHARACTERISTICS:	The iDrive™ Ultra reusable manual adapter tool is a reusable, handheld device that can be used to operate an Endo GIA™ adapter manually. It can be used to complete a firing, retract the knife and open the jaws, and to articulate an Endo GIA™ reload. It is not intended to initiate a reload firing.
MATERIALS:	The iDrive™ Ultra reusable manual adapter tool is not intended for patient contact. The iDrive™ Ultra reusable manual adapter tool are comprised of materials that are in accordance with ISO 10993-1.
PERFORMANCE DATA:	Verification and validation activities were performed and these activities are described in Section 11: Declarations of Conformity and Summary Reports. These evaluations demonstrate that the iDrive™ Ultra reusable manual adapter tool, and the iDrive™ Ultra system as a whole, functions as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 18, 2012

COVIDIEN, Formerly US Surgical A Division Of Tyco
% Ms. Sarah Rizk
Regulatory Affairs Product Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K123318
Trade/Device Name: IDrive™ Ultra powered handle and Endo GIA™ adapter
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: December 06, 2012
Received: December 11, 2012

Dear Ms. Rizk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123318

Device Name: iDrive™ Ultra powered handle and Endo GIA™ adapter

Indications For Use:

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The iDrive™ Ultra powered handle and Endo GIA™ adapter, when used with the Endo GIA™ Radial Reload with Tri-Staple™ Technology, has applications in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

Prescription Use ___X____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123318